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## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Parts 9 and 721**

**[EPA-HQ-OPPT-2010-0573; FRL-9915-60]**

**RIN 2070-AJ73**

### **Benzidine-Based Chemical Substances; Di-*n*-pentyl Phthalate (DnPP); and Alkanes, C<sub>12</sub>–13, Chloro; Significant New Use Rule**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** Under the Toxic Substances Control Act (TSCA), EPA is promulgating a significant new use rule (SNUR) to add nine benzidine-based chemical substances to the existing SNUR on benzidine-based chemical substances. With respect to both the newly-added benzidine-based chemical substances and the previously-listed benzidine-based chemical substances, this rule makes inapplicable the exemption relating to persons that import or process substances as part of an article. EPA is also promulgating a SNUR for di-*n*-pentyl phthalate (DnPP) and a SNUR for alkanes, C<sub>12-13</sub>, chloro. These actions require persons who intend to manufacture (defined by statute to include import) or process these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing such manufacture or processing. The required notifications will provide EPA with the opportunity to evaluate activities associated with a significant new use and, if necessary based on the information available at that time, an opportunity to protect against potential unreasonable risks, if any, from that activity before it occurs. EPA is also making a technical amendment to the codified list of control numbers for approved information collection activities

so that it includes the control number assigned by the Office of Management and Budget (OMB) to the information collection activities contained in this rule.

**DATES:** This final rule is effective [*insert date 60 days after date of publication in the Federal Register*].

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2010-0573, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), EPA Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Sara Kemme, National Program Chemicals Division (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-0511; email address: [kemme.sara@epa.gov](mailto:kemme.sara@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Executive Summary**

#### *A. Does this Action Apply to Me?*

These three different SNURs may apply to different entities. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities.

1. *Benzidine-based chemical substances*. You may be potentially affected by this action if you manufacture (defined by statute to include import), or process, including as part of an article, any of the benzidine-based chemical substances listed in Tables 1 and 2 of the regulatory text in this document. Potentially affected entities may include, but are not limited to:

- Manufacturers or processors of one or more of the subject chemical substances.
- Entities which plan to use the listed chemical substances in conjunction with apparel and other finished products made from fabrics, leather, and similar materials.
- Entities which plan to use the listed chemical substances in conjunction with paper and allied products.
- Manufacturers or processors of the subject chemical substances in printing inks.

These entities may include those described by the NAICS codes 325-chemical manufacturing, 31-textile manufacturers, 316-leather and allied products manufacturers, 322-paper manufacturers, 4243-apparel, piece goods, and notions wholesalers, or 443-clothing and accessories stores.

2. *DnPP*. You may be potentially affected by this action if you manufacture (defined by statute to include import), or process DnPP. Potentially affected entities may include, but are not limited to: Chemical industry – plastic material and resins (NAICS code 325211).

3. *Alkanes, C<sub>12-13</sub>, chloro (CAS No. 71011-12-6)*. You may be potentially affected by this action if you manufacture or process the following short-chained chlorinated paraffin (SCCP): Alkanes, C<sub>12-13</sub>, chloro (CAS No. 71011-12-6). Potentially affected entities may include, but are not limited to: Manufacturers of SCCPs (NAICS codes 325 and 325998), chemical

manufacturing; including miscellaneous chemical product and preparation manufacturing; and processors of SCCPs (NAICS codes 324 and 324191), petroleum lubricating oil and grease manufacturing.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 721.20) and must comply with the export notification requirements in 40 CFR part 707, subpart D.

To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 721.5 for SNUR-related obligations and with respect to benzidine-based chemical substances, the applicability provisions in Unit V. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. What Is the Agency's Authority for Taking this Action?*

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B)

requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

*C. What Action is the Agency Taking?*

In a **Federal Register** proposed rule published on March 28, 2012 (77 FR 18752) (FRL-8865-2), EPA proposed three chemical specific SNURs being addressed in this final rule (Ref. 1). EPA's response to public comments received on the proposed rule appears in Unit X. Please consult the March 28, 2012 **Federal Register** proposed rule (Ref. 1) for further background information for this final rule.

These final SNURs will require persons to notify EPA at least 90 days before commencing the manufacture (including import) or processing of:

- The nine benzidine-based chemical substances identified in Table A of Unit II., which are being added to 40 CFR 721.1660 with a designation of any use as a significant new use;
- DnPP with a designation of any use other than as a chemical standard for analytical experiments as a significant new use; and
- Alkanes, C12-13, chloro (CAS No. 71011-12-6) with a designation of any use as a significant new use.

In addition, this final rule amends the SNUR at 40 CFR 721.1660 to make inapplicable the exemption at 40 CFR 721.45(f) for persons that import or process benzidine-based chemical substances as part of an article. For the benzidine-based chemical substances, the elimination of the article exemption at 40 CFR 721.45(f) will require persons to notify EPA at least 90 days before commencing processing or importing as part of an article any of the newly-added benzidine-based chemical substances, as well as those already covered (61 FR 52287, October 7, 1996 (FRL-5396-6), codified at 40 CFR 721.1660) (Ref. 2).

*D. Why is the Agency Taking this Action?*

These SNURs are necessary to ensure that EPA receives timely advance notice of any future manufacturing and processing of these chemical substances for new uses that may produce changes in human and environmental exposures. The rationale and objectives for this SNUR are explained in Unit III.

*E. What are the Estimated Incremental Impacts of this Action?*

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of the chemical substances included in this final rule. This analysis, which is available in the docket, is discussed in Unit IX., and is briefly summarized here. In the event that a SNUN is submitted, costs are estimated to be less than \$8,700 per SNUN submission for large business submitters and \$6,300 for small business submitters. These estimates include the cost to prepare and submit the SNUN and the payment of a user fee. In addition, for persons exporting a substance that is the subject of a SNUR, a one-time notice must be provided for the first export or intended export to a particular country, which is estimated to cost less than \$100 on average per notification. The rule may also affect firms that import or process articles that may contain benzidine-based chemicals, because, while not required by the SNUR, these parties may take additional steps to determine whether benzidine-based chemicals are part of the articles that they are considering to import or process. Since EPA is unable to predict whether anyone might engage in future activities that would require reporting, potential total costs were not estimated.

**II. Overview of the Chemical Substances Subject to this Rule**

The SNURs in this final rule involve certain benzidine-based chemical substances in the existing SNUR at 40 CFR 721.1660 (Ref. 1), the nine benzidine-based chemical substances listed in Table A of this unit, DnPP (CAS No. 131-18-0), and alkanes, C12-13, chloro (CAS No. 71011-12-6).

**Table A.—Newly Added Benzidine-Based Chemical Substances**

<b>CAS or accession number</b>	<b>C.I. name</b>	<b>C.I. number</b>	<b>Chemical name</b>
117-33-9	Not available	Not available	1,3-Naphthalenedisulfonic acid, 7-hydroxy-8-[2-[4'-[2-(4-hydroxyphenyl)diazenyl]][1,1'-biphenyl]-4-yl]diazenyl]-
65150-87-0	Not available	Not available	1,3,6-Naphthalenetrisulfonic acid, 8-hydroxy-7-[2-[4'-[2-(2-hydroxy-1-naphthalenyl)diazenyl]][1,1'-biphenyl]-4-yl]diazenyl]-, lithium salt (1:3)
68214-82-4	Direct Navy BH	Not available	2,7-Naphthalenedisulfonic acid, 5-amino-3-[2-[4'-[2-(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)diazenyl]][1,1'-biphenyl]-4-yl]diazenyl]-4-hydroxy-, sodium salt (1:2)
72379-45-4	Not available	Not available	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[2-[4'-[2-[2-hydroxy-4-[(2-methylphenyl)amino] phenyl]diazenyl]][1,1'-biphenyl]-4-yl]diazenyl]-6-(2-phenyldiazenyl)-
Accession No. 21808 CAS No. CBI (NA)	CBI	CBI	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy [[[substituted phenylamino]] substituted phenylazo] diphenyl]azo-, phenylazo-, disodium salt. (generic name)
Accession No. 24921 CAS No. CBI (NA)	CBI	CBI	4-(Substituted naphthalenyl)azo diphenyl azo-substituted carbopolycycle azo benzenesulfonic acid, sodium salt. (generic name)
Accession No. 26256 CAS No. CBI (NA)	CBI	CBI	4-(Substituted phenyl)azo biphenyl azo-substituted carbopolycycloazo benzenesulfonic acid, sodium salt. (generic name)
Accession No. 26267 CAS No. CBI (NA)	CBI	CBI	4-(Substituted phenyl)azo biphenyl azo - substituted carbopolycycle azo benzenesulfonic acid, sodium salt. (generic name)
Accession No. 26701 CAS No. CBI (NA)	CBI	CBI	Phenylazoaminohydroxynaphthalenylazobiphenylazo substituted benzene sodium sulfonate. (generic name)

CAS = Chemical Abstracts Services. CBI = Confidential Business Information. CBI (NA) = Confidential Business Information (Not Available). C.I. = Chemical Index.

### **III. Rationale and Objectives**

#### *A. Rationale*

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to issue a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency's action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use.

1. *Benzidine-based chemical substances.* As described in the proposal (Ref. 1), EPA is concerned about potential carcinogenic effects on workers and consumers from the manufacture, processing, or use of these substances. Consumers exposed via dermal exposure to consumer products containing the benzidine-based chemical substances are a particular concern because enzymes present in the human body and in bacteria on the skin aid in the reduction of these chemical substances to the benzidine unit, an established human carcinogen (Ref. 3). The main consumer products that could result in dermal exposure if containing these chemical substances include textiles and leather products because they are in prolonged contact with human skin.

During the review of information on benzidine-based chemical substances, EPA determined that the newly identified chemical substances that are being added to 40 CFR 721.1660 by this final rule present the same concerns (Ref. 4) as those of the benzidine-based chemical substances already listed in the rule ((Ref. 2)), codified at 40 CFR 721.1660). EPA does not believe there is any current use of these nine benzidine-based chemical substances within or outside the United States. This conclusion is based on a review of EPA's own



Inventory Update Reporting (IUR) data, and more recent Chemical Data Reporting (CDR) data as well as other sources including the Colour Index International, published by the Society of Dyers and Colourists and American Association of Textile Chemists and Colorists; IHS Chemical Economics Handbook, Dyes; and ICIS Directory of World Chemical Producers.

In addition, as discussed earlier, although some of the benzidine-based chemical substances subject to the 1996 SNUR may be manufactured or processed outside the United States, an analysis of the benzidine-based chemical substances market (Ref. 4) revealed no information indicating import of articles containing benzidine-based chemical substances for non-excluded purposes.

Although it appears there is no ongoing domestic manufacture of the nine newly added benzidine-based chemical substances, or import for a non-excluded use of articles containing any benzidine-based chemical substances, the manufacture (including import) or processing of the nine newly added benzidine-based chemical substances and the import or processing of articles containing any benzidine-based chemical substances may begin at any time, without prior notice to EPA. Thus, EPA is concerned that commencement of the manufacture (including import) or processing for any new uses, including resumption of past uses, of benzidine-based chemical substances could significantly increase the magnitude and duration of exposure to humans over that which would otherwise exist currently. EPA is concerned that such an increase should not occur without an opportunity for the Agency to evaluate activities associated with a significant new use and an opportunity to protect against potential unreasonable risks, if any, from exposure to the chemical substance.

Accordingly, EPA is finalizing a SNUR for the nine benzidine-based chemical substances by adding them to those currently listed at 40 CFR 721.1660, and making inapplicable the article exemption at 40 CFR 721.45(f) for those chemical substances newly added in this rulemaking as

well as for those already listed at 40 CFR 721.1660. This final rule will require persons who intend to manufacture (including import) or process any of the benzidine-based chemical substances for a non-excluded use, including importing or processing any listed benzidine-based chemical substance for a non-excluded use as part of an article, to submit a SNUN.

2. *DnPP*. As described in the proposal (Ref. 1), EPA has concerns regarding potential adverse human health and environmental effects that may be caused by DnPP. EPA has direct information from animal studies that DnPP specifically can elicit developmental/reproductive effects that are relevant to human health and also indicate potential effects in wildlife. EPA also is concerned that due to its general structure and categorization as a phthalate that DnPP may elicit adverse environmental effects similar to those described for other phthalates. EPA is concerned that any manufacturing (including import) or processing of DnPP, beyond that for its limited ongoing use as a chemical standard for laboratory use, could significantly increase the magnitude and duration of exposure to humans over that which would otherwise exist currently. EPA is concerned that such an increase should not occur without an opportunity to evaluate activities associated with a significant new use and an opportunity to protect against potential unreasonable risks, if any, from exposure to the chemical substance. Accordingly, EPA is finalizing a SNUR for DnPP that would designate, as a significant new use, any use of the chemical substance other than use as a chemical standard for analytical experiments. A person who intends to manufacture or process DnPP for use other than use as a chemical standard for analytical experiments would be required to submit a SNUN.

3. *Alkanes, C12-13, chloro (CAS No. 71011-12-6)*. As described in the proposal (Ref. 1), EPA has a primary concern regarding adverse environmental effects that may be caused by alkanes, C12-13, chloro (CAS No. 71011-12-6), one type of SCCP. For example, alkanes, C12–13, chloro, have been shown to be highly toxic to aquatic invertebrates following acute and

chronic exposures and to fish following chronic exposures. EPA also has concerns about the persistence and bioaccumulation potential of SCCPs, including alkanes, C12–13, chloro, since these substances have been measured in a variety of biota (i.e., freshwater aquatic species, marine mammals, and avian and terrestrial wildlife) and have also been measured in human breast milk from Canada and the United Kingdom. The mechanisms or pathways by which SCCPs, including alkanes, C12-13, chloro (CAS No. 71011-12-6), move into and through the environment and humans are not fully understood, but are likely to include releases from manufacturing of the chemicals, manufacturing of products like plastics or textiles, aging and wear of products like sofas and electronics, and releases at the end of product life (e.g., disposal, recycling).

EPA believes that all manufacture and processing into the United States of alkanes, C12-13, chloro (CAS No. 71011-12-6) has ceased. Given that EPA has no evidence to suggest that there is any manufacture or processing of this chemical substance in the United States, and taking into consideration the negative commercial and regulatory environment associated with this chemical internationally (including the European Union (EU) and Canadian ban on marketing) and use of the alkanes, C12-13, chloro (CAS No. 71011-12-6) domestically, EPA does not expect to find such activity. However, EPA is concerned that commencement of the manufacture or processing for any new uses, including resumption of past uses, could significantly increase the magnitude and duration of exposure to humans over that which would otherwise exist. EPA is concerned that such an increase should not occur without an opportunity to evaluate activities associated with a significant new use and an opportunity to protect against potential unreasonable risks, if any, from exposure to the chemical substance. Accordingly, EPA is finalizing a SNUR for alkanes, C12-13, chloro (CAS No. 71011-12-6) that designates as a significant new use any use of the chemical substance. This SNUR requires a person who intends

to manufacture or process alkanes, C12-13, chloro (CAS No.71011-12-6) for any use to submit a SNUN.

### *B. Objectives*

Based on the considerations described in the proposal (Ref. 1) and in the response to public comments, EPA expects to achieve the following objectives with regard to the significant new uses that are designated in this final rule:

1. EPA will receive notice of any person's intent to manufacture or process the specified chemicals for the described significant new uses before that activity begins;

2. EPA will have an opportunity to review and evaluate data submitted in the SNUN before the notice submitter begins manufacturing or processing of the specified chemicals for the described significant new use;

3. EPA will be able to regulate prospective uses of the specified chemicals before the described significant new uses occur, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6 or 7; and

4. EPA would receive a notice alerting the Agency to a reversal of an industry trend toward deselecting for a chemical.

## **IV. Significant New Use Determination**

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.

- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what constitutes a significant new use of the benzidine-based chemical substances, DnPP, and alkanes, C12-13, chloro (CAS No. 71011-12-6) subject to this rule, EPA considered relevant information about the toxicity of these substances, likely human exposures and environmental releases associated with possible uses, and the four factors listed in section 5(a)(2) of TSCA. EPA has determined that the manufacture or processing, of any of the benzidine-based chemical substances subject to the 1996 SNUR or being newly added to 40 CFR 721.1660 by this final rule, except for ongoing uses specified in 40 CFR 721.1660(a)(2)(i) of the regulatory text in this document, is a significant new use. EPA has also determined that the manufacture or processing of DnPP for any use other than use as a chemical standard for analytical experiments is a significant new use, and the manufacture or processing of alkanes, C12-13, chloro (CAS No. 71011-12-6) for any use is a significant new use.

## **V. Applicability of the General Provisions**

General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule.

Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 721.1(c), persons subject to SNURs must comply with the same notice requirements and EPA

regulatory procedures as submitters of Premanufacture Notices (PMNs) under TSCA section 5(a)(1)(A). In particular, these requirements include the information submissions requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6 or 7 to control the activities on which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

However, 40 CFR 721.45(f) (which generally exempts persons importing or processing a substance as part of an article) will not apply to the benzidine-based chemical substances listed at 40 CFR 721.1660 and those added by this final rule. Therefore, a person who imports or processes as part of an article a benzidine-based chemical substance that is covered by this rule would not be exempt from submitting a SNUN.

Persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. Persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B.

## **VI. Applicability of the Final Rule to Uses Occurring Before the Effective Date of the Final Rule**

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376) (FRL-3658-5) (Ref. 5), EPA has decided that the intent of section 5(a)(1)(B) of TSCA is best served by

designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements, because a person could defeat the SNUR by initiating the proposed significant new use before the rule became final, and then argue that the use was ongoing as of the effective date of the final rule. Thus, persons who begin the commercial manufacture or processing of a covered substance as a significant new use have to cease any such activity as of the effective date of the rule if and when finalized. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires. If a person were to meet the conditions of advance compliance under 40 CFR 721.45(h), that person would be considered to have met the requirements of the final SNUR for those activities.

## **VII. Test Data and Other Information**

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. There are two exceptions:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)) and
2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a section 4 test rule or a section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 721.25, and 40 CFR 720.50). However, as a general matter, EPA recommends that SNUN submitters include data that would permit a reasoned evaluation of risks posed by the chemical

substance during its manufacture, import, processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific data it believes may be useful in evaluating a significant new use. SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA would take action under TSCA section 5(e) to prohibit or limit activities associated with this chemical. SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on:

- Human exposure and environmental releases that may result from the significant new uses of the chemical substance.
- Potential benefits of the chemical substance.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

## **VIII. SNUN Submissions**

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 721.25 and 720.40. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

## **IX. Economic Analysis**

### *A. SNUNs*

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of these chemicals and for articles containing any of the benzidine-based chemical substances included in the 1996 SNUR and those newly added by this final rule



when imported or processed as part of an article. These economic analyses, which are briefly summarized here, are available in the docket for this rule. EPA added additional information to the economic analysis for the benzidine-based chemical substances in response to public comments.

The costs of submission of a SNUN would be incurred when a company decides to pursue a significant new use of one of these chemicals. In the event that a SNUN is submitted, costs are estimated at approximately \$8,600 per SNUN submission, and include the cost for preparing and submitting the SNUN, recordkeeping, and the payment of a user fee. Businesses that submit a SNUN are either subject to a \$2,500 user fee required by 40 CFR 700.45(b)(2)(iii), or, if they are a small business with annual sales of less than \$40 million when combined with those of the parent company (if any), a reduced user fee of \$100 (40 CFR 700.45(b)(1)). In its evaluation of this final rule, EPA also considered the potential costs a company might incur by avoiding or delaying the significant new use in the future, but these costs have not been quantified.

#### *B. Export Notification*

EPA regulations under TSCA section 12(b) (15 U.S.C. 2611(b)) at 40 CFR part 707, subpart D require that, for chemicals subject to a proposed or final SNUR, a company notify EPA of the first export or intended export to a particular country of an affected chemical substance. EPA estimated that the one-time cost of preparing and submitting an export notification to be \$84. The total costs of export notification would vary per chemical, depending on the number of required notifications (i.e., number of countries to which the chemical is exported).

#### *C. Import or Processing Benzidine-based Chemical Substances as Part of an Article*

In the case of the benzidine-based chemical substances, this rule makes inapplicable the exemption relating to persons that import or process substances as part of an article. In the

proposed rule EPA preliminarily determined, based on the Agency's market research, that there was no ongoing manufacturing (including import) or processing of these chemical substances for significant new uses as part of articles or otherwise. For the nine newly-added benzidine-based chemical substances, EPA found no evidence of manufacture either domestically or abroad, and thus also no evidence of importation or processing of these chemical substances as part of articles (Ref. 1). For the majority of the 24 previously listed benzidine-based chemical substances, EPA found no evidence of manufacture, either domestically or abroad. While EPA found that some of the previously listed benzidine-based chemical substances were being manufactured domestically for discrete uses that are not subject to this SNUR, EPA found no evidence that these chemical substances were being imported or processed as part of articles (Ref. 1). EPA received no public comments indicating otherwise. Based on the global trend away from using these chemical substances, the fact that they are regulated in numerous jurisdictions, and the absence of public comments indicating their ongoing use for significant new uses, EPA is finalizing its determination that these benzidine-based chemical substances are not being manufactured (including import) or processed for a significant new use as part of articles or otherwise.

However, the rule may affect firms that plan to import or process types of articles that benzidine-based chemicals are potentially a part of. Some firms have an understanding of the contents of the articles they import or process. However, EPA acknowledges that importers and processors of articles may have varying levels of knowledge about the chemical content of the articles that they import or process. These parties may need to become familiar with the requirements of the rule. And, while not required by the SNUR, these parties may take additional steps to determine whether benzidine-based chemicals are part of the articles that they are considering to import or process. This determination may involve activities such as gathering information from suppliers

along the supply chain, and/or testing samples of the article itself. Costs vary across the activities chosen and the extent of familiarity a firm has regarding the articles it imports or processes. Cost ranges are presented in the “Economic Analysis of the Final Significant New Use Rule for Nine Benzidine Based Chemical Substances” (Ref. 4). Given existing regulatory limitations on certain benzidine-based substances both internationally and within the U.S., industry-wide processes, resources that support companies in understanding and managing their supply chains, and evidence showing minimal worldwide availability of the dyes regulated under the SNUR, EPA believes that article importers that choose to investigate their products would incur costs at the lower end of the ranges presented in the Economic Analysis as a result of this rule. For those companies choosing to undertake actions to assess the composition of the articles they import or process, EPA expects that in all likelihood, these importers and processors would take actions that are commensurate with the company’s perceived likelihood that a chemical substance might be a part of an article they intend to import into the United States and the resources it has available.

## **X. Response to Public Comment**

The Agency reviewed and considered all comments received related to the proposed rule. Copies of all non-CBI comments are available in the docket for this action. A discussion of the major comments germane to the rulemaking and the Agency’s responses follow

### *A. Legal Authority to Make Inapplicable the Exemption for Persons who Import or Process Chemical Substances as Part of Articles.*

One commenter suggests that if chemical substances are not exempted from the SNUR at the point they are incorporated into articles, then EPA should consider whether it is inappropriately regulating “articles under the chemical management authorities of TSCA,” (emphasis original) inconsistent with Congressional intent in enacting TSCA. The commenter

argues further that the regulation of articles is not the primary purpose of TSCA and that such regulation should be addressed by other agencies operating under other statutes such as the Occupational Safety and Health Act of 1970 and the Consumer Product Safety Act of 1972. Another comment raises similar issues.

EPA responded that the SNUR for benzidine-based chemical substances does not regulate articles per se, but rather persons who manufacture or process these chemical substances, including when the chemical substances are present as part of articles. TSCA clearly contemplates such regulation, as certain articles are expressly removed from TSCA jurisdiction at TSCA section 3(2). Indeed, EPA has a long history of regulating chemical substances as part of articles under TSCA. For polychlorinated biphenyls (the only chemical substance specifically addressed in TSCA as it was originally enacted), section 6(e) of TSCA provides authority for EPA to promulgate rules related to polychlorinated biphenyls in articles, such as electrical transformers. Other examples include the regulation of asbestos (40 CFR 763.160) and regulation of manufacturers of consumer products intended for use by children who also manufacture (including import) lead (40 CFR 716.21(a)(8)).

TSCA section 5 provides EPA with authority to regulate chemical substances, including chemical substances that are part of articles.<sup>1</sup> Under this section, EPA has previously regulated persons that import or process chemical substances as part of articles, including articles containing erionite fiber (40 CFR 721.2800) and mercury (40 CFR 721.10068). This is in keeping with the statutory language authorizing the Administrator to designate a “use of a

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<sup>1</sup> It should be noted that there is no general SNUN exemption for uses of a chemical substances involving articles and EPA routinely defines significant new uses to include use in articles. The exemption at 40 CFR 721.45(f) relates to a different question: whether the SNUR applies to persons who process or import a chemical substance by processing or importing the substance as part of an article.

chemical substance as a significant new use” and to require SNUN submissions from persons that intend to manufacture or process a chemical for a designated significant new use.

The commenter is incorrect in suggesting that regulation to address chemical substances in articles is beyond the originally intended functions of TSCA. When TSCA was being drafted, legislators characterized it as “a mechanism to protect against dangerous chemical materials contained in consumer and industrial products”; by way of example, the drafters cited “the presence of mercury in such consumer products as paint, home thermometers, sponges, and a variety of other products.” S. Rep. No. 94-698, 94th Cong., 2d Sess., 5-6 (1976).

Furthermore, this application of the regulations (to persons who manufacture or process the chemical substance as part of articles) is consistent with legislators’ observation, in drafting this section, that:

[T]he most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs before commercial production begins. Not only is human and environmental harm avoided or alleviated, but the cost of any regulatory action in terms of loss of jobs and capital investment is minimized.

H.R. Rep. 94-1679, 94th Cong., 2d Sess., 65 (1976).

When a chemical substance is domestically produced, the substance generally exists in non-article form at the earliest point of commercial production in the United States. When a chemical substance is imported, however, it may in many instances already be part of an article, even at the earliest point that it enters U.S. commerce. By this action, EPA makes importers of specific chemical substances subject to the same SNUN requirements as domestic manufacturers of the same substance, irrespective of whether such import is as part of an article. This action is consistent with the plain text of TSCA 5(a)(1)(B) (generally, “no person may . . . manufacture or process” for a significant new use without proper notice) and with one of the intended goals of TSCA: to hold importers to “the same responsibilities and obligations as domestic

manufacturers,” H.R. Rep. No. 94-1341, 94th Cong. 2d. Sess., 12-13 (1976). This action is also consistent with EPA’s identified concerns regarding benzidine-based chemical substances when they are present as part of an article (See Ref. 1, pg. 18756).

Moreover, when originally promulgating the presumptive SNUN submission exemption for persons who import or process chemical substances as part of articles (40 CFR 721.45(f)), EPA did so based on a belief that people and the environment would generally not be exposed to chemical substances in articles. To address those cases where the assumption may not be valid, EPA specifically noted that, “EPA may decide to eliminate one or all of these . . . exemptions [including the exemption for importers and processors of chemicals as part of articles] if EPA decides that review under a SNUR is warranted for specific substances . . . in articles.” (Ref. 6). Thus, while EPA clearly has statutory authority to subject importers and processors of chemical substances in articles to SNUN requirements, they are presumptively excluded by rule at 40 CFR 721.45(f), based on an assumption that people and the environment will generally not be exposed to substances in articles. (Ref. 6). To the extent that potential exposure to a chemical substance as part of an article contributes to the EPA’s determination pursuant to the factors in section 5(a)(2) of TSCA that the new use is significant (i.e., EPA has reason to anticipate that use as part of an article would raise important questions, related to potential exposure, that EPA should have an opportunity to review before such use could resume or occur), it is appropriate to make the exemption inapplicable.

EPA notes that one of the commenters appears to have conflated the **Federal Register** notice establishing the article importers’ and article processors’ exemption from PMN requirements (Ref. 7), discussing 40 CFR 720.22(b)) with another **Federal Register** notice establishing the comparable exemptions from SNUR requirements (Ref. 6), discussing 40 CFR 721.45(f)). While EPA recognizes that parts 720 and 721 deal with many similar issues, they are

also distinct from each other in important respects. It is significant that in the 1984 action, whereby EPA established the article importers' and article processors' exemption for SNURs, it did not simply mirror the 1983 rationale for the comparable exemption from PMN obligations. For PMNs, EPA noted the difficulties associated with determining the identity and Inventory status of each chemical substance in imported articles (e.g., automobiles) (Ref. 7). But for SNURs, EPA placed special emphasis on its assumption that import of the substance as part of an article would not affect human or environmental exposure to the substance, while taking particular care to reserve ongoing discretion to revise its assumption as warranted in the case of specific substances. EPA had reason to differentiate between the two rationales. SNURs are for specified chemical substances for which EPA has identified exposure-based concerns for the defined significant new use (per the TSCA section 5(a)(2) factors). By contrast, PMNs are required for all new chemicals (i.e., those not on the TSCA inventory), not a specified set of chemicals.

Finally, there is no basis for the commenter's suggestion that EPA should decline to review significant new uses, in deference to the Occupational Safety and Health Administration (OSHA) or the Consumer Product Safety Commission (CPSC), simply because a significant new use notice would be submitted by a person who imports or processes the chemical substance as part of an article. Neither the Occupational Safety and Health Act of 1970 nor the Consumer Product Safety Act of 1972 contains a comparable mechanism to ensure advance notice and opportunity to review significant new uses of chemical substances, as part of articles or otherwise.

*B. Development of a Separate Policy Framework for Making Inapplicable the Exemption for Persons who Import or Process Chemical Substances as Part of Articles*

1. *Comment.* Some commenters suggest that before finalizing a rulemaking to make the “articles exemption” inapplicable to the benzidine-based chemical substances, the EPA should complete a separate public comment process to develop a general “policy framework for the issuance of article SNURs.” Commenters suggest that this policy framework should include science based criteria, feasibility criteria, costs, and other factors.

One comment suggests that, in formulating the “policy framework” or criteria for making the exemption for importers and processors of chemical substances as part of articles inapplicable, EPA should address the following questions:

- Can the risk posed by the chemical of concern be addressed through the standard regulation?
- Why is the standard approach for SNURs that exempts articles not sufficient?
- What conditions make direct regulation of articles necessary?
- What gaps in health and environmental protection are likely to occur if a SNUR only regulates chemicals and mixtures?

*Response.* The comments conflate two separate issues: The determination of a significant new use under TSCA section 5(a)(2), and the decision to make the regulatory exemption at 40 CFR 721.45(f) inapplicable. (40 CFR 721.45(f) provides that persons who import or process a chemical substance as part of an article are not subject to the notification requirements at 40 CFR 721.25; this exemption is referred to as the “articles exemption” by some commenters). EPA first makes a determination on whether a use of a chemical substance is a significant new use considering the factors listed in TSCA section 5(a)(2). Once that determination is made, EPA separately determines whether it would be appropriate to revoke the regulatory exemption at 40 CFR 721.45(f) for persons who import or process a chemical substance as part of an article.



EPA notes that there may be a variety of cases in which it may be appropriate for EPA to include persons who import or process the chemical substance as part of an article among the persons subject to SNUN submission obligations. Knowledge regarding chemical exposures from articles has evolved since the Agency established the exemption at 40 CFR 721.45(f) in 1984, and there has been a steady increase in international trade of chemicals in articles. Accumulated data illustrate that SNURs (and section 5(e) consent orders) that include the exemption for persons who import or process a chemical substance as part of an article are sometimes insufficient to appropriately flag significant new exposures from downstream uses. For example, there have been instances in which a section 5(e) consent order for a new chemical substance was issued, prohibiting the release of the chemical substance to water, and yet the chemical substance at issue was later found in the environment and biota. The presence of the chemical substance in the environment and in biota then appears to be associated with the use of the substance in articles (Ref. 8). There are also documented exposures (and resulting toxicity) of children to lead and cadmium and their compounds from a variety of articles, such as toys (Ref. 9), and exposures to other heavy metals from articles, as measured in indoor air and house dust samples, which are direct routes of exposure accounting for children's levels and toxicity (Ref. 10). Other well-documented examples are the presence of brominated flame retardants (e.g., polybrominated diphenyl ethers and brominated phthalates and benzoates) in samplings of articles, indoor air, people, and house dust. The low exchange rate of indoor air and house dust to sources outside the home support the flame retardant release from articles postulate. Likewise, other semi-sealed environments, such as automobiles, have demonstrated migration of flame retardants from treated articles to interior surfaces and indoor air, as no other source was possible. In addition, high flame retardant levels have been observed in biota raised in proximity to articles and living near article recycling sites. Further, observed flame retardant levels in biota

and in the environment at locations remote from manufacturing sites suggest transport of these non-volatile chemical substances on associated particulate matter from distributed treated articles, which strongly suggest release from articles as one potential source (Ref. 11-15).

The information discussed in this unit – the well-documented exposures (and resulting toxicity) of children to lead, cadmium, and other metals from a variety of articles; the data on other chemicals used in articles; and the presence in the environment and biota of certain brominated flame retardants (e.g., polybrominated diphenyl ethers and brominated phthalates and benzoates) – all illustrate that there can be exposure to the chemicals associated with their presence in articles (Refs. 9-15).

The scope of the suggested criteria (which the commenters suggest EPA should now develop to govern its exercise of its authority to make the exemption at 40 CFR 721.45(f) inapplicable) is incommensurate with the level of analysis supporting the original development of the exemption. EPA notes that TSCA section 5(a)(1) establishes a general prohibition on manufacturing or processing a chemical substance for a significant new use without prior notice to EPA. 40 CFR 721.45(f) establishes an exemption from this prohibition, but it is based on a fairly minimal rationale: “EPA believes people and the environment will generally not be exposed to substances in articles.” (Ref. 6). EPA counterbalanced its reliance on this generalized assumption (about all chemicals that exist as part of articles) with a broad reservation of case-by-case discretion to make the exemption inapplicable as “warranted for specific substances.” (Ref. 6).

EPA does not think that development of a “policy framework” is necessary before reaching the conclusion, with respect to benzidine-based chemical substances, that persons who import or process these substances as part of articles should be subject to the notification provisions of 40 CFR 721.25. Dermal exposure can occur from the leaching of the benzidine-

based chemical substances by sweat in contact with the dyed textiles (Ref. 1)). In addition, data indicate that exposure to other chemicals in materials such as textiles and foam can result from the dust that is generated from abrasion and/or degradation of the materials (Ref. 16). EPA notes that the commenter did not offer data to undercut the conclusion that such exposure can occur. Because of this information, and other information described in Unit III.E. of the (Ref. 1), EPA does not assume that new types or forms of exposure associated with new use of benzidine-based chemical substances would be insignificant merely because the chemical substance is imported or processed as part of an article. Thus, EPA does not believe the default assumption used to support 40 CFR 721.45(f) (that people and the environment will generally not be exposed to substances in articles) holds with respect to benzidine-based chemical substances.

2. *Comment.* Comments also suggest that EPA analyze the “variety of products” that could be construed as articles, the “practical questions that will arise” if the import and processing of such products were not exempt from SNURs, and the “unique channels of trade,” through which different varieties of products move. Commenters encouraged EPA to develop and articulate publicly a policy framework, considering the following factors on an article-specific basis, before proceeding to revoke the article exemption with respect to a particular chemical substance:

- Whether there is, or will be, direct exposure to the chemical substance in the article during the course of the article’s use.
- Whether there is, or will be, a release of the regulated substance, or a metabolite or breakdown product from the substance, during subsequent processing, distribution, use or disposal of the article.
- Whether there is, or will be, a link between import or export of an article and cross-border exposure to the U.S. population.

*Response.* Given the variety of substances and uses addressed under SNUR regulations, EPA believes it is more efficient to address article-specific issues as they actually arise within each regulatory action than to develop, as suggested by the commenter, an anticipatory “policy framework” document.

The importers and processors of chemical substances present in articles are generally in the best position to know which chemical substances are used in which types of articles. When EPA identifies a particular chemical substance in a SNUR, such stakeholders have an opportunity to identify, in their public comments, any article-specific issues that concern them. Furthermore, these issues are likely to be more accurately identified and more appropriately addressed in connection with the development of a SNUR for particular chemical substances than they would be if they were reviewed generically. In this case, commenters did not raise any issues specific to certain articles.

*C. A Compelling Basis Standard for Making Inapplicable the Exemption for Persons who Import or Process Chemical Substances as Part of Articles*

1. *Comment.* Some commenters made the point that revocation of the exemption at 40 CFR 721.45(f) should not be a presumed component of all SNURs. This was part of a broader comment that EPA should not make this exemption inapplicable unless there was a “compelling basis” to do so. One commenter was concerned that if EPA proceeds on a case-by-case basis, following reasoning that “could be applied to many chemicals,” then elimination of the exemption would come to be a “kind of ‘default’ step” in future SNURs. One commenter also argues that, where the SNUN submission requirement is to apply to importers and processors of substances as part of articles, the TSCA section 5(a)(2) criteria require EPA to undertake a compelling analysis of how the use and distribution of the “specific articles or article categories,” would “contribute to potential exposures of concern.”

*Response.* As an initial matter, the comments conflate two separate issues: The determination of a significant new use under TSCA section 5(a)(2), and the decision to make the regulatory exemption at 40 CFR 721.45(f) inapplicable. The TSCA section 5(a)(2) factors do not impose a “compelling analysis” requirement on the elimination of the 40 CFR 721.45(f) exemption because (among other reasons) these two actions concern two discrete issues. The section 5(a)(2) factors speak to the significant new use itself. 40 CFR 721.45(f) speaks to who is required to notify EPA of the significant new use.

In this case, EPA identified its reasons, under the TSCA section 5(a)(2) factor analysis, to anticipate that the new use would pose important new questions related to the substances’ potential to threaten health or the environment (Ref. 1, pg. 18756), and that EPA should have an opportunity to consider those questions before such use could occur. (In essence, a SNUR puts a particular set of uses on the same footing as a new chemical, which is subject to automatic review under TSCA section 5(a)(1) unless EPA specifically excludes it from such review.) EPA also identified a basis, specific to benzidine-based chemical substances, to question the assumption that people and the environment will generally not be exposed to the chemical substances in articles. Therefore, EPA is also making inapplicable the exemption at 40 CFR 721.45(f) for persons who import or process a chemical substance as part of an article. No commenter provided data or other information to undercut the factual basis for either decision.

Neither TSCA nor the implementing regulations for SNURs establish a separate “compelling basis” standard, either with respect to the determination of a significant new use or with respect to the decision to make the exemption at 40 CFR 721.45(f) inapplicable. Nor have commenters identified a persuasive basis for EPA to adopt such a standard under either scenario.

EPA’s specific action with respect to benzidine-based chemical substances is not, as commenters suggest, tantamount to the presumptive revocation of the SNUN submission

exemption for importers and processors of chemical substances as part of articles in all future instances. EPA has not proposed to globally modify or eliminate the SNUR exemption for persons who import or process chemical substances as part of articles. EPA need not presently address the merits of an action it is not presently taking, and did not previously propose to take.

TSCA sections 5(a)(2)(B) and (C) require EPA to consider the extent to which a new use “changes the type or form of exposure” or “increases the magnitude and duration of exposure” before making a determination that a particular use is a “significant new use.” EPA disagrees that it must therefore, as one commenter suggests, conduct a multiplicity of separate significant new use analyses whenever the use under consideration involves an article (i.e., one for each specific article or article category, comparing the relative significance of each particular article or article category). In particular, the commenter’s interpretation of TSCA section 5(a)(2) misconstrues the baseline against which the “newness” and the “significance” of a significant new use are evaluated. As EPA has long maintained, the single analytical baseline is the set of uses that were ongoing “as of the date of publication” of the SNUR proposal. (See e.g., Ref. 1).

Furthermore, the particular analytical standards the commenter suggests are not commensurate with the establishment of a one-time notice requirement intended to give EPA an opportunity to later evaluate the need for testing or other regulatory action under TSCA. Requiring upfront answers to the very questions EPA would evaluate after receiving a significant new use notice, as a pre-condition of requiring the notices, would undermine the statutory authorization to issue SNURs in the first place. EPA’s decision to propose a SNUR for a particular chemical use and to make the exemption at 40 CFR 721.45(f) inapplicable to that SNUR need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency is acting because it has reason to anticipate that such use would raise important new questions related to the substance’s potential to threaten health or

the environment, and that EPA should have an opportunity to consider those questions before such use could occur. Since the use designated as a significant new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the significant new use, in articles or otherwise, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use.

Even if it were appropriate to construe the decision to make the 40 CFR 721.45(f) exemption inapplicable as a subcomponent of the significant new use determination under section 5(a)(2) (rather than as a subsequent determination), EPA adequately considered the section 5(a)(2) factors.

The first factor is the “projected volume of manufacturing and processing of a chemical substance” (TSCA section 5(a)(2)(A)). EPA projects that these substances will not be manufactured or processed at any volume for the new uses in question and notes that for the newly proposed nine benzidine-based chemical substances, data reported to EPA for the 2012, 2006, 2002, and 1998 reporting cycles, as required by the TSCA IUR rule, indicate no evidence of manufacture (including import) (Refs. 1 and 17). Any increase in the projected volume of manufacturing (including import) or processing of these substances, beyond the very limited uses currently ongoing, would reflect a significant departure from prior trends. Given that these chemical substances are anticipated to metabolize to the parent benzidine molecule, which is a known human carcinogen, EPA anticipates that information presented in the SNUN on the quantities manufactured (including imported) and processed of benzidine based chemical substances would be important to EPA’s overall evaluation of whether the new use may present an unreasonable risk to human health or the environment. The necessary increase in volume of

this substance from any new use weighs in favor of determining that the new use is a significant new use.

The second factor is "the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance" (TSCA section 5(a)(2)(B)). For the newly added benzidine-based chemical substances, a general market review on these chemical substances indicates no current manufacture within or outside the United States. Although some of the chemical substances subject to the 1996 SNUR may still have certain limited ongoing uses (e.g., as a test reagent, lab standard, or microscopy stain), such uses are expected to be confined to limited laboratory or technical applications that are not expected to represent an appreciable amount of overall exposure. Furthermore, EPA did not find evidence of actual ongoing importation or domestic production for these uses. No comments provided evidence of ongoing manufacture (including import) or processing of these chemical substances as part of articles or otherwise. Thus, EPA believes that there is no, or almost no, current exposure to these chemical substances in the United States.

Should a significant new use be planned, EPA anticipates that the new use would raise important new questions such as the following:

- To what extent would the use be expected to involve dermal contact with the substance?
- Would the substance be used in a setting where oral exposure is likely (e.g., would young children be able to mouth the article)?
- How would potential occupational exposures and releases to the environment over the substance's lifecycle be expected to be managed?

Given that these chemical substances are anticipated to metabolize to the parent benzidine molecule, which is a known human carcinogen, EPA anticipates that the answers to such questions would be important to EPA's evaluation of whether the new use may present an



unreasonable risk to human health or the environment. The potential for a new use to change the type or form of exposure weighs in favor of determining that the new use is a significant new use.

The third factor is "the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance" (TSCA section 5(a)(2)(C)). Should one of the designated significant new uses be planned, EPA anticipates that the planned new use would raise important new questions relating to the concentration in which the substance would be used, the potential for repeated exposure, and the potential for continuous exposure. Given these chemical substances are anticipated to metabolize to the parent benzidine molecule, which is a known human carcinogen, EPA anticipates that the answers to these questions would be important to EPA's overall evaluation of whether the new use may present an unreasonable risk to human health or the environment. EPA also notes that dermal exposure can occur from the leaching of the chemical substances by sweat in contact with the dyed textiles (Ref. 1). Because of this information, and the information described in Unit III.E. of the proposal (Ref. 1), EPA does not assume that new types or forms of exposure associated with new use of these substances would be insignificant merely because they relate to new use in an article or because the pertinent manufacturing or processing of the substance occurred as part of an article. The potential for activities related to a new use to increase the magnitude and duration of exposure weighs in favor of determining that any non-ongoing use is a significant new use.

The fourth factor is "the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance" (TSCA section 5(a)(2)(D)). EPA anticipates that any new use, beyond the very limited uses currently ongoing, would raise important new questions such as the following:

- To what extent can the anticipated manufacturing, processing, distribution in commerce, and disposal of the chemical substance be expected to result in worker exposure, user exposure, or release of the chemical substance to the environment?
- What potential controls are available to limit such releases?

Given these chemical substances are anticipated to metabolize to the parent benzidine molecule, which is a known human carcinogen, EPA anticipates that the answers to these questions would be important to EPA's overall evaluation of whether the new use "may present an unreasonable risk to human health or the environment." The potential for manufacturing, processing, distribution in commerce or disposal of these benzidine-based chemical substances to change the overall exposure picture weighs in favor of determining that consumer textile use is a significant new use.

After considering each of the four TSCA 5(a)(2) factors, EPA has concluded that the factors taken together weigh in favor of determining that manufacture or processing of these benzidine-based chemical substances for any non-ongoing use would be a significant new use such that the Agency should have an opportunity to analyze the new use before such use (and potential exposures) occurs. This determination would still hold even if one were to consider the 40 CFR 721.45(f) exemption as a subcomponent of the significant new use determination under section 5(a)(2).

*D. Narrowing the Scope of SNURs where the Exemption for Importers and Processors of Chemical Substances as Part of Articles is Made Inapplicable*

Some comments suggest that significant new uses should not be "open-ended" but instead must be targeted to specific articles, particularly in cases where the exemption at 40 CFR 721.45(f) is made inapplicable. The concern expressed is that if the SNUN applies to "any use of a substance, then regulated parties and the EPA would be obligated to proceed through the

SNUR process for an article that would have little relevance to the perceived hazard that drove the original SNUR.” The commenter further writes that “open-ended article SNUR’s can trigger reviews for articles that may have no relationship to the hazard or exposure concerns that motivated EPA’s decision to initiate the rule.”

EPA’s concern with these benzidine-based dyes is not limited to certain exposure pathways to specific articles. EPA’s concern is specific to the benzidine-based dyes and thus to the range of exposures that could occur for these chemical substances. The preamble of the proposed rule notes multiple potential routes and sources of exposure including inhalation, skin absorption via dyed textiles, and ingestion. (Ref. 1). Furthermore, SNURs need not be narrowly focused on the mitigation of currently foreseeable exposure scenarios—it is proper that they will also ensure EPA has timely notice of future (and currently unforeseeable) exposure scenarios. An additional requirement to make targeted predictions of the particular uses that "may be proposed in the future" would undermine this intended function of the SNUR.

More generally, an exhaustive list of all applications that could possibly fall within the ambit of a significant new use definition is not a prerequisite for issuing a SNUR. Since the significant new use does not currently exist, deferring a detailed consideration of potential risks related to the importation or processing of these chemical substances (including as part of articles) is an effective use of resources. If a person decides to begin importing or processing the chemical, as part of an article or otherwise, the notice to EPA allows EPA to evaluate the significant new use according to the specific parameters and circumstances surrounding that intended use.

*E. EPA Should Have a Reasonable Basis to Conclude that Identified Articles Would be Distributed in the United States*

One comment states that “EPA presents an exposure-based rationale for why certain articles could be a concern, but indicates that there is no current expectation that these chemical substances will be used in such articles.” The commenter believes that before issuing an article SNUR, EPA should have a reasonable basis to conclude that identified articles of concern would be distributed in the United States. The commenter contends that EPA should identify an article containing such a chemical that is currently in global commerce and explain why it is likely to be distributed in the United States. The commenter believes that it might also be possible to identify an article at the research and development stage that is likely to proceed to commercial development. Without such findings, however, the commenter is concerned that EPA would be issuing an article SNUR for a situation that presents no current or likely future threats to health or the environment, and thus that the rule would be a waste of public resources. Another comment raises similar issues, arguing that EPA should provide even more specific information on how the significant new uses contribute to risk.

Alternatively, the first commenter suggests that EPA include a specific provision suspending enforcement of the SNUR until a determination is made that there is a reasonable basis to believe that an article containing the specific chemical had been, or would be, distributed in the United States.

EPA disagrees with the suggestion to limit the application of SNUN submission requirements for importers and processors of the chemical substances as part of articles to situations where importation or processing as part of an article is known to be imminent. SNURs address situations in which EPA is concerned about the potential for use to commence without prior opportunity for review and risk management action where appropriate. For purposes of SNURs, EPA cannot be expected to predict specific situations where new uses may be imminent, or how those specific uses may contribute to risk, before designating significant new uses. The

purpose of a SNUR is to obtain such information so that EPA can evaluate risks associated with, and take risk management action where appropriate regarding, any notified activities. These rules serve the important function of alerting EPA when a significant new use is intended. Without them, EPA would have no expectation of timely identification of new uses of these chemicals. Notice relating to the import or processing of articles is particularly important in this case, as the proposal specifically identified a concern related to the potential for dermal exposure via dyed articles (i.e., from the leaching of the benzidine-based chemical substances by sweat in contact dyed articles, such as textiles). (Ref. 1).

It would not be an efficient use of government resources for EPA to continually monitor global commerce to try to predict which chemicals are about to be imported as part of articles (but have not yet been imported) into the United States. Persons who wish to manufacture (including import) or process these chemical substances for a significant new use, as part of an article or otherwise, are in a better position than EPA to evaluate when they are about to initiate a particular significant new use.

Given that SNURs cannot be issued for ongoing uses, the commenter's suggestion (that EPA must itself make an upfront demonstration that a particular new use is *about to begin*, to secure the opportunity to be notified of when significant new uses involving importation or processing of chemical substances as part of articles are about to begin) is impracticable. It would likely result in a scenario in which an otherwise significant new use would be allowed to commence prior to the issuance of a SNUR proposal, thereby placing that use outside of EPA's SNUR authority. Furthermore, EPA has already considered and rejected (in 2006, following public comment on a 2004 proposal) the position that it must defer revocation of the 40 CFR 721.45(f) exemption for a SNUR until it appears likely "that these chemical substances will be imported as part of articles." (Ref. 18). EPA concluded in 2006, after a re-evaluation of the issue

prompted by public comments, that “if the subject substances when imported as a part of articles are not subject to the SNUR, EPA could miss the opportunity to obtain notifications that would provide information of potential regulatory and assessment value.” (Ref. 19)(ultimately declining to make the exemption inapplicable, based on a separate concern that the use with respect to articles appeared to be already ongoing).

Finally, for essentially the same reasons as set forth in this unit, EPA believes it would be inappropriate to follow one commenter’s alternative suggestion: to promulgate a SNUR without the exemption for importers and processors of chemical substances as part of articles, while somehow “suspending enforcement” until the precise moment that manufacture or processing for a significant new use as part of an article is about to begin, but has not yet begun.

In sum, EPA believes commenter’s suggestions would turn the regulatory process on its head. EPA would likely need to already have a SNUR in place in order to obtain the kind of timely information about significant new use that the commenter asserts should be prerequisite to issuing the SNUR in the first place.

#### *F. Intended Coverage of the Benzidine-Based Chemical Substances SNUR*

1. *Comment.* One commenter writes that “A proposed rule offering a clear explanation of what uses EPA intends to cover, including an explanation of the alternatives if certain situations are unclear, will greatly increase the chances that useful information about business practices and common terms of art in an industry will be identified.” EPA should define the scope of the uses to be regulated as clearly and precisely as possible.

The commenter also contended that soliciting public comment on the appropriate scope of new uses to be regulated, for a specific chemical substance, constitutes “an abdication of the role that EPA should be undertaking.” The commenter suggests that before soliciting public comments, EPA should have first pursued an informal coordination with downstream industries

and (as necessary) an exercise of its “ample authority under TSCA, either through regulatory action under section 8 or order authority under section 11 (c).” Finally, the commenter suggests that to the extent the proposed significant new uses admit ambiguity or potential need for adjustment in response to public comment, that is evidence that EPA “should have learned more about the uses” before issuing the proposal and is improperly seeking “to shift the responsibility to stakeholders.”

*Response.* The description of the scope of the significant new uses in the benzidine-based chemical substances proposed SNUR and the Agency’s basis for the proposal were explicit. The SNUR proposal fairly apprised stakeholders as to the chemical at issue and the particular concerns driving the proposed action. It further indicated that based on information available to EPA, the significant new uses identified are not currently on-going. Stakeholders had an opportunity to oppose any of these preliminary findings by supplying countervailing information thorough the rulemaking process itself. Grafting additional pre-proposal steps onto the SNUR rulemaking process would be unnecessarily time-consuming and an unsound use of agency resources. The timelier, less resource-intensive, and more transparent process is for interested stakeholders, through the public comment process itself, to simply provide any pertinent countervailing information they wish to add to the initial collection of information EPA presented in the proposal.

As noted earlier, TSCA section 5(a)(2) does not compel nor contemplate an article by article analysis to identify every conceivable significant new use of a chemical substance. EPA evaluates whether a new use is “significant” consistent with the evidence of Congressional intent underlying the enactment of TSCA. See H.R. Rep. No. 94-1341 at 24 (1976) (“[B]ecause of the nature of a substance, it is possible that any new use of it will be significant. Thus, a potentially dangerous substance which is manufactured for a particular use may, if manufactured for a

different use present additional health or environmental problems and consequently there should be notice of the intent to manufacture it for such different use.” H.R. Rep. No 94-1679 at 66 (1976) (“[T]he conferees intend that any potential threats to health or the environment from the manufacture, processing, distribution in commerce, or disposal of a substance associated with a new use be considered by the Administrator when determining the significance of a new use.”) Finally, a broad construction of the significant new use is particularly appropriate where (as in the case of benzidine-based dyes) any increase in the projected volume of manufacturing (including import) or processing of these substances, beyond the very limited uses currently ongoing, would reflect a significant departure from prior trends.

2. *Comment.* “It does not make sense to issue article SNUR’s [sic] for full size machines or structures. An article SNUR should focus on the specific components of more complex machines or structures that involve the chemical of concern.”

*Response.* The commenter neither explains what the commenter means by “full size,” nor offers any specific evidence to support their general view that new uses of chemical substances in “full size machines or structures,” are any less likely to be significant than new uses of chemical substances in “specific components.” Nor does the commenter indicate why persons who import or process chemical substances as part of articles would be more likely to be importing or processing the chemical substances for use in “full size” articles. Attempting to define and distinguish between “full size” article uses and other uses, and correlating such distinctions to whether persons are importing or processing these chemical substances as part of articles, would delay the rulemaking and increase its complexity, in a manner that does not seem warranted on the basis of the limited information supplied in the comment.



3. *Comment.* “Chemicals used in articles may sometimes be incorporated into 'internal' mechanisms of the article that are unlikely to come into contact with people or be released into the environment during normal use of the article.”

*Response.* The commenter does not explain why the basis for a SNUR should be limited to those exposures that occur concurrent with the article fulfilling its intended function, when TSCA section 5(a)(2)(D) contemplates that EPA will consider the value of ensuring it has a future opportunity to review the whole life-cycle impact (e.g., “manufacturing, processing, distribution in commerce, and disposal”) of a significant new use of a chemical substance. The exposure to the chemical substance, including when it is in an article, may be larger during disposal or recycling than during the “normal use” of the chemical. Further, chemical substances that are ‘internal’ to an article may still result in exposure if the chemical substance has certain physical- chemical properties (e.g., a relatively volatile chemical used as a plasticizer in interior automobile parts) or due to abrasion of the article (e.g., a dye incorporated into furniture covering.)

Nor does the commenter indicate why persons who import or process chemical substances as part of articles would be more likely than any other manufacturers or processors to be manufacturing or processing for use in the internal mechanisms of articles. Attempting to define and meaningfully distinguish between “internal” article uses and other uses, and correlating such distinctions to whether manufacturing or processing of the substance occurs as part of an article, would delay the rulemaking and increase its complexity, in a manner that does not seem warranted on the basis of the limited information supplied in the comment.

4. *Comment.* “EPA should clarify whether the SNUR applies to articles containing the chemical of concern in a solid, liquid, particle or gaseous form.”

*Response.* This SNUR applies to the chemical substances regardless of form. To the extent the commenter seeks to continue some aspect of the exemption at 40 CFR 721.45(f), depending on the form of the chemical substance in the article that is being imported or processed, the commenter has not offered any specific support for that proposition, either generally or in any particular case. In the SNUR at issue, EPA does not believe it is prudent to limit the application of the rule based on the form (solid, liquid, or gaseous) of the chemical substances at issue. Chemicals that may have been used in one form during the manufacture of the article may be released from the article in a different physical form. Also, fluids and particles are not covered under the applicable definition of article at 40 CFR 704.3. EPA received no comments suggesting that use of these chemicals in one form or another may not be significant based on the TSCA section 5(a)(2) factors. Moreover, information relevant to a specific form of a chemical substance can be submitted in a SNUN and may be considered by EPA in review of that SNUN in determining whether follow-up action is warranted, and may support EPA's amendment of the SNUR to limit its scope.

5. *Comment.* “[A] chemical may be present at a very low concentration that is unlikely to be associated with a risk warranting EPA risk management action. . . . EPA should consider whether it can establish a *de minimus* exclusion [from the SNUR].”

*Response.* EPA notes that the SNUR already contains a general exemption for unintentionally present impurities at 40 CFR 721.45(d). To the extent chemical substances are intentionally added to articles at very low concentrations, the question of whether the substance warrants risk management action is one that EPA can address upon receipt of the SNUN, not an analytical prerequisite to deciding whether it should receive the SNUN in the first place.

#### *G. Screening for Benzidine-Based Chemical Substances*

Some commenters faulted the proposal for not identifying precise screening operations to be taken in response to the SNUR, and for not conducting additional analyses of the cost and feasibility of such screening operations. One commenter suggests, in particular, that an article importer should be deemed in compliance with the SNUR if the chemical is present below an established *de minimis* level (based on mass or concentration), or if it simply does not know the article's content after conducting a reasonable inquiry for such information.

With respect to processors, given the requirements of 40 CFR 721.5(a)(2), a processor of the chemical substance should have received notification that the chemical substance is the subject of a SNUR. A processor is not required to submit a SNUN for its unknowing processing of a chemical substance subject to a SNUR if (upon obtaining knowledge) the processor can document that when the past processing occurred, the processor neither knew the chemical identity of the substance it was processing nor knew that substance was subject to a SNUR. See 40 CFR 721.5(c). EPA would generally expect that processors would only fail to be aware of the presence of a chemical subject to a SNUR if the manufacturer (including importer) or upstream processor of the chemical substances failed to meet their obligations under 40 CFR 721.5(a)(2).

With respect to importers, EPA disagrees that it would be appropriate or necessary for the SNUR itself to define screening procedures to be employed for compliance purposes. The Agency did not propose to require a particular screening procedure and, for the following reasons, it does not agree that particular screening procedures should be specified and incorporated into the final rule.

First, EPA believes that adding these sort of screening-effort exemptions, specifically for importers of chemical substances as part of articles, would be especially difficult to reconcile with the general statutory prohibition (under TSCA section 5(a)(1)) on manufacturing or processing a chemical substance for a significant new use without prior notice to EPA. The issue

under the statute is whether or not an importer actually imports a substance. This is a separate question from the importers' level of knowledge or level of effort to obtain knowledge respecting the content of the imports.<sup>2</sup> With respect to SNURs, EPA notes that its direct rulemaking authority is to identify significant new uses under section 5(a)(2). The Agency has been appropriately cautious in exercising its implicit rulemaking authority to limit the applicability of section 5(a)(1). EPA recognizes that it did previously exercise such implicit rulemaking authority when establishing 40 CFR 721.45(f). However, as noted in this unit, the exemption at 40 CFR 721.45(f) was established along with a broad reservation of authority to withdraw the exemption where, as here, it is inaccurate to assume that there would not be exposure to the substance simply because it is present as part of an article. And a screening-effort exemption is especially difficult to reconcile with the statute in the case of importers. With importers, unlike with processors, there are no upstream entities with a duty under TSCA to notify importers of the presence of a chemical substance subject to a SNUR.

Second, establishing a safe-harbor for importers based on lack of knowledge would create incentives for foreign suppliers to deliberately withhold information from importers. This could greatly reduce the efficacy of this SNUR. Currently, when an importer wishes to import a substance it knows would be subject to notification requirements, but for which the chemical identity is claimed as CBI by a foreign manufacturer, EPA's longstanding practice when reviewing PMNs and SNUNs is to accept the relevant information on chemical identity directly from the foreign manufacturer. See, (Ref. 7)("[t]he principal importer need not know the specific chemical identity of the imported substance" and "may have its foreign manufacturer or supplier,

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<sup>2</sup> The limiting clause in the definition of "principal importer" at 40 CFR 721.3—"knowing that a chemical substance will be imported"—is a limit based on the person's knowledge that he or she is engaged in an import transaction, not a limit based on the person's knowledge of a particular chemical's identity and regulatory status. (48 FR 21727, May 13, 1983) (FRL 2998-5).

or some other person, report the chemical identity to EPA.”) Offering an outright regulatory exemption to an importer simply because it is ignorant of the existence of a SNUR-regulated substance in the imported article (after conducting a prescribed inquiry) would allow foreign suppliers to short-circuit this process simply by refusing to divulge to the importer whether the import contains a chemical substance subject to SNUR.

Third, to the extent the chemical substance subject to the SNUR is only “unintentionally present” at the point of foreign manufacture, it is already exempt from reporting by the importer as an imported impurity. See 40 CFR 721.3 (chapeau), 40 CFR 720.3(m), and 40 CFR 721.45(d). Thus, importers are not required to submit a SNUN for a substance based simply on that substance’s presence as an impurity (i.e., a chemical substances unintentionally present with another chemical substance).

Fourth, whether and how it may appropriate for importers to screen for benzidine-based chemical substances will depend on many factors, including their current state of knowledge about the articles that they import and the potential risk of unknowingly importing articles that contain these chemical substances. The relevant factors are largely impossible for EPA to establish at this time, given that there is currently no on-going import of these substances for the designated significant new uses.

Finally, EPA did conduct additional analysis of potential screening burden to explore commenters’ concerns. As described in Unit X.H., EPA acknowledges the costs of the various activities that certain entities may choose to undertake, in response to this rule, to ensure that the chemicals they import or process as part of articles do not trigger SNUN submission requirements (Ref. 20). Based on EPA’s economic analysis and the responses to the proposed rule, EPA does not believe that these costs will be significant for any individual entity.

*H. Costs Associated with Making the Exemption for Persons that Import or Process Chemical Substances as Part of Articles Inapplicable*

Some comments note that the economic analysis, which focuses on the cost of filing a SNUN, does not include any analysis of the costs that might be associated with screening articles to determine whether these SNURs would apply. One comment also notes that “the preambles to the proposed rules do not discuss what, if any obligations companies have to screen articles for the chemicals included in the SNUR’s.”

With respect to processors: existing SNUR regulations already provide that the unknowing processing of a chemical substance does not itself trigger SNUN requirements if the processor can (upon obtaining knowledge) document that when the past processing occurred, the processor neither knew the chemical identity of the substance it was processing nor knew that substance was subject to a SNUR. See 40 CFR 721.5(c).

With respect to importers: Based on an assessment of current market activity in the economic analysis, EPA believes that the chemicals subject to the final SNUR are not currently being imported into the United States for the identified significant new uses in articles. EPA received no public comments on the proposed SNUR that indicate that importation of these benzidine-based chemical substances for the finalized significant new uses, in articles or otherwise, is ongoing. However, because this SNUR makes inapplicable the exemption for persons that import or process chemical substances as part of articles, companies may take actions to ensure that they do not import any articles containing the subject chemical substances after promulgation of this rule, by such means they deem appropriate. This is not necessarily a new consideration for importers given that importers of mixtures have needed to be aware of chemical substances subject to a SNUR that may be a component of imported mixtures. Whether and how companies respond will depend on many factors, including their current state of

knowledge about articles that they import and their own assessments of the potential risk of unknowingly importing articles that contain these chemicals. As noted in this unit, EPA did conduct additional analysis of burdens that may be associated with activities entities may undertake to ensure the chemicals they import or process as part of articles do not trigger SNUN submission requirements (Ref. 20).

In any event, EPA did not propose to mandate any particular level of screening of imported or processed articles. The preamble to the proposed SNUR did not discuss the precise steps that an importer or processor must take in this regard because there is no precise level of screening by which the manufacturer or processor could be separately liable under the rule (if not performed) or by which a manufacturer or processor could obtain “safe harbor” from what would otherwise be a violation of the rule. While EPA might potentially take screening practices into consideration when evaluating a particular instance in which the SNUR was nevertheless violated, that would be as a matter of enforcement policy, not as a provision of the rule itself.

EPA has included estimates for some activities that importers may undertake (e.g., supplier inquiries) in order to evaluate the likelihood of chemicals being imported as part of articles. These costs will vary for individual companies and their experience with suppliers. Awareness of article components and constituents is becoming more commonplace as companies frequently operate on a global scale and are subject to numerous regulatory requirements around the world that affect product stewardship responsibilities. Existing requirements that may compel a company to investigate an article’s components include the Consumer Product Safety Act, California’s Proposition 65, and the EU’s regulation on Registration, Evaluation, Authorization and Restriction of Chemical (REACH), which requires customer notification about the presence of certain chemical in articles that a company distributes. U.S. importing companies may already be familiar with the process of determining whether the articles they import contain restricted

chemical substances, if they are subject to the requirements cited above or various U.S. regulations, such as the Product Safety Improvement Act (CPSIA) of 2008, Washington's Children's Safe Product Act, and Maine's Act to Protect Children's Health and the Environment from Toxic Chemicals in Toys and Children's Products (Ref. 20).

Given the existing regulatory limitations on certain chemicals both internationally and within the United States, regulated industries have begun to develop industry-wide processes and other resources to obtain information on chemical substances in articles. Policies and procedures could include supplier agreements, such as Hewlett Packard's requirement that suppliers meet their General Specifications for the Environment (GSE) (Ref. 21) and Walmart's requirement that suppliers participate in International Compliance Information Exchange (iCiX) to manage and share compliance information throughout the supply chain (Ref. 22). More extensive policies and procedures could even include product testing. Companies may choose to use existing procedures or develop new ones that could range from document review, to supplier agreements, to product testing.

Additional analysis conducted by EPA on activities that companies may choose to undertake to ensure that the chemicals they import or process as part of articles do not trigger requirements of the SNUR shows a wide range of potential activities and associated costs. The conduct of these activities and associated costs are at the discretion of the company. Table B of this unit shows EPA's estimated range of costs associated with some of these potential activities for importers of articles.



**Table B: Range of Costs Associated with an Importer's Identification of Chemicals Subject to SNURs in Articles**

Activity	Cost US (\$)	Notes
<b>Per Rule Costs</b>		
1. Rule familiarization	\$55	Cost typically already included in SNUR Economic Analyses
2. Identify the type of imported articles that potentially contain the restricted substances	\$130 to \$1,550	Actual costs may vary based on number of articles imported and the complexity of the article itself (number of components)
3. Identify all suppliers involved	\$950	Actual costs may vary depending on the number of articles imported, number of suppliers, and frequency of supplier changes
6. Recordkeeping	\$10	Cost typically already included in SNUR Economic Analyses
<b>Article-Related Costs</b>		
4. Collect data from suppliers	\$5 to \$515 per article reviewed. \$0 if no data collected.	Actual costs only apply to those companies that choose to collect data from suppliers. They will vary depending on the specific data collection method chosen. Total costs depend on considerations including the number of articles imported, number of suppliers, and frequency of supplier changes.
5. Chemical testing	\$130 per article tested. \$0 if no testing.	Actual costs only apply to those companies that choose to collect data from suppliers. Total costs per company will depend on considerations including the number of articles tested, which may be affected by the number of suppliers and risk associated with each, and frequency of supplier changes.

Should processors of articles need to demonstrate compliance with a SNUR, it is expected that they could use the shipping or labeling documents received with the article in the ordinary course of business. As these documents would be received and stored anyway, as per standard business practices, the elimination of the exemption in the SNUR for persons that import or process chemical substances as part of articles would be unlikely to lead such persons to incur significant additional costs. To the extent that processors choose to undertake more steps to identify regulated chemicals as part of articles, the costs of these activities would be similar to

those in Table B of this unit for importers of similar size, supply chain complexity, and level of compliance with other chemical regulations.

There are a number of regulations, including California's Proposition 65 and the EU's REACH that currently restrict or otherwise affect the use of certain benzidine-based substances, particularly in their use as dyes in textiles and leather. California's Proposition 65 Chemical List includes benzidine-based dyes as a potential carcinogen and requires that firms provide a clear and reasonable warning before knowingly and intentionally exposing anyone to a listed chemical. This warning may include the labeling of consumer products (Refs. 23-24).

The EU has banned, in textile and leather articles which may come into direct and prolonged contact with humans, the use of azo dyes which can break down to release any of 22 listed carcinogenic aromatic amines (including benzidine and its congeners) in amounts above 30 ppm (Ref. 25). The European Commission's Directorate General for Health and Consumers maintains the RAPEX database that member countries can use to report dangerous products and the measures they have taken to prevent or restrict those products. Despite the EU ban, small numbers of products containing such azo dyes have recently been listed on RAPEX. The products are typically voluntarily withdrawn from the market and/or destroyed by the importer or have been placed under an order by the authorities to cease sales (Refs. 26, 27). Therefore, azo dyes in imported articles still remain a potential issue in the EU. Other countries have also banned the manufacture and use of the azo dyes in textiles. Currently the manufacture of azo dyes is banned in South Korea and Japan (Ref. 27). Use of these chemicals is banned by Egypt, India, China, South Korea, Taiwan and Vietnam (Ref. 28), and Indonesia has banned the use of the dyes in children's and baby's clothing (Ref. 29). In 2012, the Japanese textiles and leather industry announced voluntary restrictions of the chemicals (Refs. 29, 30). Canada has also expressed concern about the potential release of benzidine or its congeners from azo dyes and is

evaluating potential approaches for addressing azo dyes (Ref. 30). Organizations, such as the American Apparel & Footwear Association (AAFA), have developed a comprehensive Restricted Substances List (RSL) as a reference for companies and have developed a toolkit to help apparel and footwear companies to better manage chemicals throughout the supply chain. Given the current level of international and domestic regulation and attention to benzidine-related chemicals, EPA believes that importers and processors of articles may already have undertaken a number of activities to manage chemicals within their supply chains and generally to deselect for these chemicals. Therefore, EPA expects that companies that could potentially commence importing or processing benzidine-based chemicals as part of articles may already have some knowledge of the chemicals within their supply chain and would undertake few of the activities listed in Table B and would fall toward the lower end of the cost range for any activities undertaken. More detailed information is included in EPA's economic analysis.

EPA does not believe that the subject chemicals are entering the United States in imported articles for the significant new uses defined by the final regulation. However, companies may screen or initiate other activities to determine if articles they import in the future contain chemicals included in this SNUR. EPA notes that no commenters provided data that could be used to estimate what, if any, costs might be associated with continued assurance that imported articles are free from the chemical substances subject to this SNUR. The number of companies that may take such actions is not known, nor is the level of action that may be taken by a particular company. Based on EPA's economic analysis and the responses to the proposed rule, EPA does not believe that these costs will be significant for any individual entity.

#### *I. Import and Export Regulations for Chemical Substances as Part of Articles*

One comment noted that EPA is not proposing to change the way in which TSCA's export and import rules (pursuant to TSCA sections 12(b) and 13, respectively) apply to articles

containing these chemical substances. The comment indicates that (under the status quo of the import rules) the U.S. Customs and Border Protection (CBP) will not be screening articles for the chemical substances in the proposed SNURs.

EPA agrees that the TSCA import rules are important TSCA compliance mechanisms and that 19 CFR 12.119 allows EPA to establish section 13 import certification requirements for chemicals in articles. However, declining to subject importers to one notice requirement (section 13 import certification) does not render another notice requirement (section 5 SNUN submission) unenforceable.

In this case, EPA did not propose to require section 13 import certification or section 12 export notification for the subject chemical substances when part of articles. This is consistent with EPA's past practice of making the exemption at 40 CFR 721.45(f) inapplicable without also requiring import certification or export notification for these chemical substances as part of articles (40 CFR 721.2800; 40 CFR 721.10068). However, the Agency continues to study this issue and has not ruled out a later proposal to require import certification and/or export notification for these chemical substances as part of articles.

With or without an import certification requirement, it is the importer that is "responsible for insuring that chemical importation complies with TSCA just as domestic manufacturers are responsible for insuring that chemical manufacture compliance with TSCA." 40 CFR 707.20(b)(1).

#### *J. Distinguishing Between Chemicals in Non-Article Form and Other Products*

One comment contends that the rule, as proposed, "would not allow [EPA] to distinguish between a chemical being brought into the United States in its raw form and a chemical being brought in on a shift as a dye or finish." The comment goes on to state that treating them the same way is unrealistic and scientifically unsound.

EPA disagrees with the comment and notes that it was not proposing to eliminate all distinctions, in all regulatory provisions under TSCA, between import of a chemical substance in non-article form, and import of a chemical substance as part of an article. The rule simply removes one particular distinction between persons who import or process a chemical substance in non-article form and persons who import or process a chemical substance as part of an article. Thus, while the raw chemical manufacturer and the article importer may both be required to submit a SNUN, EPA would be able distinguish between the two scenarios, as appropriate, in its review of the SNUN. The SNUN review process will allow case-by-case analysis of each circumstance.

With respect to the commenter's comparison of the volume at which these chemical substances are currently manufactured in non-article form and the volume at which these chemical substances are currently manufactured in article form (i.e., via import of a chemical substance as part of an article), EPA's conclusion, with respect to the significant new uses, is that the two volumes are currently the same. This is because EPA has concluded that there is no current manufacture of these chemical substances for the significant new uses, either through domestic manufacture of the substances in non-article form, or through import of articles containing the substances. Thus, both production volumes are currently zero.

#### *K. Provisions for Processors*

In a comment submitted after the closing of the public comment period, one commenter questions the utility of a provision for processors at 40 CFR 721.5(c), as applied to notice requirements under this rule. The commenter states that 40 CFR 721.5(c) would not protect companies unless they could document lack of knowledge that a SNUR applies. The commenter believes that this requirement is therefore impossible to meet, explaining that it is impossible to document what one does not know.

EPA will respond to this comment, although it was submitted after the closing of the public comment period for this action, because it relates closely to the timely submitted comments. EPA disagrees that applying 40 CFR 721.5(c) is impossible or impracticable. The provisions at 40 CFR 721.5(c) provide that the unknowing processing of a chemical substance does not itself trigger SNUN submission requirements, subject to meeting certain documentation requirements. Upon obtaining knowledge that it previously engaged in activities covered by the SNUR, a processor can at that time assemble evidence relating to the period when the past processing occurred. Specifically, this would be evidence bearing on whether the processor previously knew the chemical identity of the substance it was processing or previously knew that that substance was subject to a SNUR. Evidence to establish a prior lack of knowledge could include items such as a purchase order and, where applicable, a material safety data sheet (MSDS) that indicates neither the relevant chemical identity nor the presence of a chemical subject to a SNUR. Another type of evidence would be the affidavit of a person in a position of appropriate authority swearing to the prior lack of knowledge. EPA would generally consider the wording on a purchase order and, where applicable, an MSDS, along with an affidavit as described above, in determining whether there is sufficiently clear documentation for purposes of 40 CFR 721.5(c). However, if there was also contrary documentary evidence, indicative of the prior possession of knowledge (e.g., receipt of a notice given to the processor pursuant to 40 CFR 721.5(a)(1)(i)) then the overall documentary evidence would not allow the processor to take advantage of the provisions of 40 CFR 721.5(c).

#### *L. Potential Ongoing Use of DnPP*

One commenter identified a potential ongoing use of DnPP in grease in automotive switches. The commenter requested that EPA exclude the identified use from the SNUR.

After investigation, EPA has determined that there is no ongoing use of DnPP in grease in automotive switches.

The commenter states that “[b]ased on current use information . . . [the commenter] believes that DnPP is being used in grease in some automotive switches.” The proposal stated that EPA “welcome[d] specific information that documents [ongoing] use.” Yet the commenter does not provide any current use information to substantiate this belief. When raising a potential ongoing use, it is generally preferable to include information substantiating that use, especially where the entity raising that use is not an actual manufacturer (including importer) or processor of that chemical substance for that use and thus would not be anticipated to have direct knowledge of that use.

In order to determine whether there is an ongoing use of DnPP in grease in automotive switches, EPA performed targeted searches of sources including IHS Chemical Economics Handbook, MSDS search tools such as Seton’s MSDS Hazard Communication Library and patent searches and was unable to substantiate this use as an ongoing use of DnPP. EPA reviewed several grease MSDS, and no grease MSDS listed any phthalate in its composition. EPA’s DfE alternatives analysis also has not identified use in grease in automotive switches as an ongoing use of DnPP.

EPA also conducted patent searches for grease in automotive switches, and dampening greases in general. A patent search found mentions of the term phthalates with electronic components, but not DnPP specifically for automotive switches. However, one patent gave a very broad alkyl range that release of phthalates C4 and C8 were observed during the vacuum burn pretreatment of electronic components [disc drives]. This process is routine treatment to remove volatiles from electronic components, including electronic switches (Vacuum baking process USP 6,051,169 and Electric switches USP 3,694,601). EPA does not believe the

existence of this information is indicative of current use of DnPP in grease in automotive switches because, patents do not necessarily indicate current use. As noted in the proposed rule (Ref. 1), no IUR production volume data were reported for DnPP during the 2006, 2002, 1998 and 1994 reporting cycles. In addition, no production volume data were reported for the 2012 CDR (Ref. 17)

Accordingly, EPA is declining to exclude use “in grease in automotive switches” from the significant new uses of DnPP.

#### *M. Reliance on Inventory Update Rule (IUR) Data in Assessing Ongoing Use of DnPP*

One commenter suggests that EPA relied solely on the IUR data for determining ongoing uses of DnPP, and that such reliance may be misleading or incomplete. The commenter notes that ongoing uses below the IUR reporting threshold of 10,000 lbs would not be reported to EPA through the IUR process.

EPA uses IUR data to identify ongoing uses of chemical substances. However, this is not the sole source of information relied upon to support the SNUR. EPA first identified a SNUR as a regulatory alternative for DnPP in the Phthalates Action Plan because EPA found that the most recent IUR data contained no reports of DnPP being produced in or imported into the United States. In proposing the SNUR, EPA prepared the “Economic Analysis of the Proposed Significant New Use Rule for Di-n-pentyl Phthalate (DnPP)” (Ref. 31) and conducted internet queries in order to ascertain whether there were any ongoing uses of DnPP at levels below the IUR reporting threshold. During the course of this research EPA identified several companies which either use or sell DnPP as a chemical standard for use in phthalates testing. Accordingly, the significant new uses of DnPP does not include use of DnPP as a chemical standard for analytical experiments as a significant new use.

#### *N. Design for the Environment (DfE) Assessment for Phthalates*



One commenter noted that EPA has undertaken a DfE project focused on phthalates, including but not limited to, DnPP. The commenter believes that the DfE phthalates alternative assessment will provide valuable information about potential alternatives to industries using phthalates. The commenter recommends that EPA refrain from further action on any phthalate until the DfE project is finalized.

EPA disagrees that finalization of the DnPP SNUR should be delayed until the DfE project is complete. (To the extent the comment is discussing the timing of other potential EPA actions to address phthalates, it is outside the scope of this proposal.)

The comment states that the final DfE report would identify alternatives, their viability as substitutes, and EPA's comparative hazard information. EPA disagrees that this report is likely to provide information relevant to this SNUR. When defining the "significant new use," EPA is limited to uses of the chemical substance that are not ongoing. The DfE report is not expected to identify alternatives for chemical substances that are generally no longer in use. It is already clear that there are many alternatives to DnPP use, because there are almost no ongoing uses of DnPP. Furthermore, the DfE report is not expected to suggest DnPP itself as an alternative to another phthalate because of its toxicity relative to other phthalates. Even if the DfE report were to identify a significant new use of DnPP as an alternative to some other chemical substance, then EPA would have the opportunity to consider that information at such time as it received the significant new use notice for DnPP.

EPA notes that it is a regular practice to finalize SNURs for chemical substances that have not undergone a DfE assessment. Given that the DfE report is unlikely to provide additional information relevant to EPA's significant new use determination for DnPP, that newly available information respecting any particular use of DnPP could be included in the significant new use notice itself, and that further delay would increase regulatory uncertainty, EPA disagrees that it

would be appropriate to delay issuance of the SNUR on DnPP pending the release of the DfE report.

## **XI. References**

The following is a listing of the documents that are specifically referenced in this action. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. U.S. EPA. Proposed Rule; Benzidine-Based Chemical Substances; Di-*n*-pentyl phthalate (DnPP); and Alkanes, C12–13, Chloro; Significant New Use Rules. 77 FR 18752, March 28, 2012 (FRL-8865-2). 2. U.S. EPA. Benzidine-Based Chemical Substances; Significant New Uses of Certain Chemical Substances, 61 FR 52287, October 7, 1996 (FRL-5396-6).

3. U.S. EPA, 2010. U.S. Environmental Protection Agency. Chemical Substances Derived from Benzidine and Its Congeners, [http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/DCB%20Action%20Plan\\_06232010.noheader.pdf](http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/DCB%20Action%20Plan_06232010.noheader.pdf) (Accessed January 24, 2011).

4. U.S. EPA. Economics and Policy Branch, USEPA/OCSP/ Economics, Exposure, and Technology Division. “Economic Analysis to Support the Final SNUR for Benzidine and Benzidine-based Chemical substances.” 5. U.S. EPA. Significant New Uses of Certain Chemical Substances, 55 FR 17376, April 24, 1990 (FRL-3658-5).

6. U.S. EPA. Significant New Uses of Chemical Substances; Certain Chemicals. 49 FR 35014, September 5, 1984 (FRL-2541-8).

7. U.S. EPA. Premanufacture Notification; Premanufacture Notice Requirements and Review Procedures. 48 FR 21722, May 13, 1983 (FRL 2998-5).

8. Testimony of James J. Jones, Acting Assistant Administrator Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency before the Committee on Environment and Public Works and the Subcommittee on Superfund, Toxic and Environmental Health United States Senate, July 24, 2012, available at [http://www.epa.gov/ocir/hearings/pdf/2012\\_jjones\\_testimony1.pdf](http://www.epa.gov/ocir/hearings/pdf/2012_jjones_testimony1.pdf).

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11. Stapleton, et al., 2008, Alternate and New Brominated Flame Retardants Detected in U.S. House Dust, *Environ. Sci. Technol.*

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13. Muller, et al., 2011, Car Indoor Air Pollution- Analysis of Potential Sources, *Journal of Occupations Medicine and Toxicology* 2011, 6:33.

14. Wu, et al., 2009, Residues of Polybrominated Diphenyl Ethers in Frogs (*Rana limnocharis*) from a Contaminated Site, South China: Tissue Distribution, Biomagnification, and Maternal Transfer, *Environ. Sci. Technol.* 2009, 42: 5212-5217.

15. Gaylor, et al. 2012, House Crickets Can Accumulate Polybrominated Diphenyl Ethers (PBDEs) Directly from Polyurethane Foam Common in Consumer Products, *Chemosphere*, 2012, 86: 500-505.

16. Covaci, et al. 2006, Hexabromocyclododecanes (HBCDs) in the Environment and Humans: A Review. *Environ. Sci. Technol.* 2006, 40: 3679-3688.

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*[http://java.epa.gov/oppt\\_chemical\\_search/](http://java.epa.gov/oppt_chemical_search/)*.

16. U.S. EPA, Certain Polybrominated Diphenylethers; Proposed Significant New Use Rule. 69 FR 70409, December 6, 2004 (FRL 7633-1).

19. U.S. EPA, Certain Polybrominated Diphenylethers; Significant New Use Rule. 71 FR 34018, June 13, 2006 (FRL 7743-2).

20. U.S. EPA, Understanding the Costs Associated with Eliminating Exemptions for Articles in SNURs, May 1, 2013.

21. Hewlett-Packard Development Company, LP. (2010). "International Material Data System." Retrieved from *<http://www.mdssystem.com/>*.

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*<http://www.walmartstores.com/Suppliers/248.aspx>*.

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*[http://oehha.ca.gov/prop65/prop65\\_list/files/P65list020813.pdf](http://oehha.ca.gov/prop65/prop65_list/files/P65list020813.pdf)*.

24. CAEPA, 2013b. State of California Environmental Protection Agency. Proposition 65 in Plain Language! February 2013. *<http://oehha.ca.gov/prop65/background/p65plain.html>*.

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26. European Commission. 2010. *RAPEX – Latest Notifications*. Directorate General for Health and Consumers. [http://ec.europa.eu/consumers/dynex/rapex/rapex\\_archives\\_en.cfm](http://ec.europa.eu/consumers/dynex/rapex/rapex_archives_en.cfm).

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31. Environment Canada. 2009. *Strategic options for the management of toxic substances benzidine and 3,3-dichlorobenzidine*. Available at: <http://www.ec.gc.ca/toxics/docs/sor/bdine/EN/sum.cfm> (Accessed 10 September, 2009).

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34. U.S. EPA. Modification of Significant New Use Rules for Certain Substances, 62 FR 42690, August 8, 1997 (FRL-5735-4).

## **XII. Statutory and Executive Order Reviews**

### *A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This final rule has been designated by OMB as a “significant regulatory action” under section 3(f) of Executive Order 12866 (58 FR 51735, October 4, 1993). Accordingly, EPA submitted this action to OMB for review under Executive Order 12866 and 13563 (76 FR 3821, January 21, 2011), and any changes made in response to OMB recommendations are documented in the docket.

### *B. Paperwork Reduction Act (PRA)*

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq.* Burden is defined in 5 CFR 1320.3(b). The information collection activities associated with existing chemical SNURs are already approved by OMB under OMB control number 2070-0038 (EPA ICR No. 1188); and the information collection activities associated with export notifications are already approved by OMB under OMB control number 2070-0030 (EPA ICR No. 0795). If an entity were to submit a SNUN to the agency, the annual burden is estimated to be less than 100 hours per response, and the estimated burden for an export notifications is less than 1.5 hours per notification. In both cases, burden is estimated to be reduced for submitters who have already registered to use the electronic submission system. Additional burden, estimated to be less than 10 hours, could be incurred where additional record keeping requirements are specified under 40 CFR 721.125(a), (b), and (c).

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control

numbers for EPA's regulations in Title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9 and included on the related collection instrument, or form, if applicable. EPA is amending the table in 40 CFR part 9 to list this SNUR. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of the PRA and OMB's implementing regulations at 5 CFR part 1320. Since the existing OMB approval was previously subject to public notice and comment before OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend the table is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), to amend this table without further notice and comment.

*C. Regulatory Flexibility Act (RFA)*

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, I hereby certify that promulgation of this SNUR will not have a significant economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows.

EPA generally finds that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities (See, e.g., Ref. 34). Since these SNURs will require a person who intends to engage in such activity in the future to first notify EPA by submitting a SNUN, no economic impact will occur unless someone files a SNUN to pursue a significant new use in the future or forgoes profits by avoiding or delaying the significant new use. Although some small entities may decide to engage in such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a handful of notices per year. During the six year period from 2005-2011, only three submitters self-identified as small in their SNUN submission

(Refs. 5, 32, 33). EPA believes the cost of submitting a SNUN is relatively small compared to the cost of developing and marketing a chemical new to a firm and that the requirement to submit a SNUN generally does not have a significant economic impact.

A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a “significant new use.” In the proposed SNUR EPA preliminarily determined, based in part, on the Agency’s market research, that these chemical substances are not being manufactured (including imported) or processed for a significant new use. In the case of the benzidine-based dyes, this preliminary determination also included importation and processing of these chemical substances as part of articles (Ref. 1). EPA received no public comment indicating any ongoing importation of the benzidine-based chemical substances as part of articles or otherwise. Therefore, EPA is finalizing its determination that these uses, including the importation and processing of benzidine-based dyes as part of articles, are new and not ongoing. Thus no small entities presently engage in a significant new use.

Therefore, EPA believes that the potential economic impact of complying with this SNUR is not expected to be significant or adversely impact a substantial number of small entities.

#### *D. Unfunded Mandates Reform Act (UMRA)*

Based on EPA’s experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reason to believe that any State, local, or Tribal government would be impacted by this rulemaking. As such, EPA has determined that this regulatory action would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of UMRA, 2 U.S.C. 1531-1538.

#### *E. Executive Order 13132: Federalism*



This action does not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

*F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have Tribal implications because it will not have any effect (i.e., there will be no increase or decrease in authority or jurisdiction) on Tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, Executive Order 13175 (65 FR 67249, November 9, 2000), does not apply to this action.

*G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this action is not intended to address environmental health or safety risks for children.

*H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not expected to affect energy supply, distribution, or use.

*I. National Technology Transfer and Advancement Act (NTTAA)*

Since this action does not involve any technical standards, section 12(d) of NTTAA, 15 U.S.C. 272 note, does not apply to this action.

*J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994), because EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. This action does not affect the level of protection provided to human health or the environment.

*K. Congressional Review Act (CRA)*

Pursuant to the CRA, 5 U.S.C. 801 *et seq.*, EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects**

*40 CFR Part 9*

Environmental protection, Reporting and recordkeeping requirements.

*40 CFR Part 721*

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: December 16, 2014.

Wendy C. Hamnett,

*Director, Office of Pollution Prevention and Toxics.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 9--[AMENDED]**

1. The authority citation for part 9 continues to read as follows:

**Authority:** 7 U.S.C. 135 *et seq.*, 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. In § 9.1, add the following sections in numerical order under the undesignated center heading “Significant New Uses of Chemical Substances” to read as follows:

**§ 9.1 OMB approvals under the Paperwork Reduction Act.**

\* \* \* \* \*

40 CFR citation	OMB control No.
* * *	* *
<b>Significant New Uses of Chemical Substances</b>	
* * *	* *
721.10226	2070-0038
721.10227	2070-0038
* * *	* *

\* \* \* \* \*

**PART 721--[AMENDED]**

3. The authority citation for part 721 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

4. Revise § 721.1660 to read as follows:

**§ 721.1660 Benzidine-based chemical substances.**

(a) *Chemical substances and significant new uses subject to reporting.* (1) The benzidine-based chemical substances listed in Table 1 and Table 2 of this section are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

**Table 1— Benzidine-Based Chemical Substances**

CAS or accession number	C.I. name	C.I. number	Chemical name
117-33-9	Not available	Not available	1,3-Naphthalenedisulfonic acid, 7-hydroxy-8-[2-[4'-[2-(4-hydroxyphenyl)diazenyl]][1,1'-biphenyl]-4-yl]diazenyl]-
65150-87-0	Not available	Not available	1,3,6-Naphthalenetrisulfonic acid, 8-hydroxy-7-[2-[4'-[2-(2-hydroxy-1-naphthalenyl)diazenyl]][1,1'- biphenyl]-4-yl]diazenyl]-, lithium salt (1:3)
68214-82-4	Direct Navy BH	22590	2,7-Naphthalenedisulfonic acid, 5-amino-3-[2-[4'-[2-(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)diazenyl]][1,1'-biphenyl]-4-yl]diazenyl]-4-hydroxy-, sodium salt (1:2)
72379-45-4	Not available	Not available	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[2-[4'-[2-[2-hydroxy-4-[(2-methylphenyl)amino]phenyl]diazenyl]][1,1'-biphenyl]-4-yl]diazenyl]-6-(2-phenyldiazenyl)-
Accession No. 21808 CAS No. CBI (NA)	CBI	CBI	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy [[[substituted phenylamino]] substituted phenylazo] diphenyl]azo-, phenylazo-, disodium salt. (generic name)
Accession No. 24921 CAS No.	CBI	CBI	4-(Substituted naphthalenyl )azo diphenyl azo-substituted carbopolycycle azo benzenesulfonic acid, sodium salt. (generic name)

Accession No. 26256 CAS No. CBI (NA)	CBI	CBI	4-(Substituted phenyl)azo biphenyl azo-substituted carbopolycycloazo benzenesulfonic acid, sodium salt. (generic name)
Accession No. 26267 CAS No. CBI (NA)	CBI	CBI	4-(Substituted phenyl)azo biphenyl azo - substituted carbopolycycle azo benzenesulfonic acid, sodium salt. (generic name)
Accession No. 26701 CAS No. CBI (NA)	CBI	CBI	Phenylazoaminohydroxynaphthalenylazobiphenylazo substituted benzene sodium sulfonate. (generic name)

**Table 2—Benzidine-Based Chemical Substances**

CAS number	C.I. name	C.I. number	Chemical name
92–87–5	Benzidine	Not available	[1,1'-Biphenyl]-4,4'-diamine
531–85–1	Benzidine · 2HCl	Not available	[1,1'-Biphenyl]-4,4'-diamine, dihydrochloride
573–58–0	C.I. Direct Red 28	22120	1-Naphthalenesulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[4-amino-, disodium salt
1937–37–7	C.I. Direct Black 38	30235	2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diaminophenyl) azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt
2302–97–8	C.I. Direct Red 44	22500	1-Naphthalenesulfonic acid, 8,8'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[7-hydroxy-, disodium salt
2429–73–4	C.I. Direct Blue 2	22590	2,7-Naphthalenedisulfonic acid, 5-amino-3-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-4-hydroxy-, trisodium salt
2429–79–0	C.I. Direct Orange 8	22130	Benzoic acid, 5-[[4'-[(1-amino-4-sulfo-2-naphthalenyl) azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
2429–81–4	C.I. Direct Brown 31	35660	Benzoic acid, 5-[[4'-[[2,6-diamino-3-[[8-hydroxy-3,6-disulfo-7-[(4-sulfo-1-naphthalenyl)azo]-2-naphthalenyl]azo]-5-methylphenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, tetrasodium salt
2429–82–5	C.I. Direct Brown 2	22311	Benzoic acid, 5-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl) azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt

2429-83-6	Direct Black 4	30245	2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diamino-5-methylphenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt
2429-84-7	C.I. Direct Red 1	22310	Benzoic acid, 5-[[4'-[(2-amino-8-hydroxy-6-sulfo-1-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
2586-58-5	C.I. Direct Brown 1:2	30110	Benzoic acid, 5-[[4'-[[2,6-diamino-3-methyl-5-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium
2602-46-2	C.I. Direct Blue 6	22610	2,7-Naphthalenedisulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[5-amino-4-hydroxy-, tetrasodium salt
2893-80-3	C.I. Direct Brown 6	30140	Benzoic acid, 5-[[4'-[[2,4-dihydroxy-3-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
3530-19-6	C.I. Direct Red 37	22240	1,3-Naphthalenedisulfonic acid, 8-[[4'-[(4-ethoxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-7-hydroxy-, disodium salt
3567-65-5	C.I. Acid Red 85	22245	1,3-Naphthalenedisulfonic acid, 7-hydroxy-8-[[4'-[[4'-[(4-methylphenyl)sulfonyl]oxy]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-, disodium salt
3626-28-6	C.I. Direct Green 1	30280	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-6-(phenylazo)-, disodium salt
3811-71-0	C.I. Direct Brown 1	30045	Benzoic acid, 5-[[4'-[[2,4-diamino-5-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
4335-09-5	C.I. Direct Green 6	30295	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-6-[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-3-[(4-nitrophenyl)azo]-, disodium salt
6358-80-1	C.I. Acid Black 94	30336	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[[4'-[[4-hydroxy-2-[(2-methylphenyl)amino]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-6-[(4-sulfophenyl)azo]-, trisodium salt

6360-29-8	C.I. Direct Brown 27	31725	Benzoic acid, 5-[[4'-[[4-[(4-amino-7-sulfo-1-naphthalenyl)azo]-6-sulfo-1-naphthalenyl]azo][1,1'-biphenyl]-4-yl] azo]-2-hydroxy-, trisodium salt
6360-54-9	C.I. Direct Brown 154	30120	Benzoic acid, 5-[[4'-[[2,6-diamino-3-methyl-5-[(4-sulfophenyl)azo]phenyl] azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-3-methyl-, disodium salt
8014-91-3	C.I. Direct Brown 74	36300	Benzoic acid, 3,3'-[(3,7-disulfo-1,5-naphthalenediyl)bis [azo(6-hydroxy-3,1-phenylene)azo[6(or7)-sulfo-4,1-naphthalenediyl]azo[1,1'-biphenyl]-4,4'-diylazo]]bis[6-hydroxy-, hexasodium salt
16071-86-6	C.I. Direct Brown 95	30145	Cuprate(2-), [5-[[4'-[[2,6-dihydroxy-3-[(2-hydroxy-5-sulfophenyl)azo]phenyl] azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxybenzoato(4-)-, disodium salt

(2) The significant new uses are:

(i) For each of the chemical substances listed in Table 2 of this section, any use other than use as a reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; and, additionally for Colour Index (C.I.) Direct Red 28 (Congo Red) (CAS No. 573-58-0), an indicator dye.

(ii) For the chemical substances listed in Table 1 of this section: Any use.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Revocation of certain notification exemptions.* The provisions of § 721.45(f) do not apply to this section. A person who imports or processes a chemical substance identified in paragraph (a)(1) of this section as part of an article for a significant new use described in paragraph (a)(2) of this section is not exempt from submitting a significant new use notice.

(2) [Reserved]



5. Add § 721.10226 to subpart E to read as follows:

**§ 721.10226 Di-*n*-pentyl phthalate (DnPP).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as di-*n*-pentyl phthalate (DnPP) (1,2-benzenedicarboxylic acid, 1,2-dipentyl ester) (CAS No. 131-18-0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new use is: Any use other than use as a chemical standard for analytical experiments.

(b) [Reserved]

6. Add § 721.10227 to subpart E to read as follows:

**§ 721.10227 Alkanes, C<sub>12-13</sub>, chloro (CAS No. 71011-12-6).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alkanes, C<sub>12-13</sub>, chloro (CAS No. 71011-12-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new use is: Any use.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Persons who must report.* Section 721.5 applies to this section except for § 721.5(a)(2). A person who intends to manufacture for commercial purposes a substance identified in paragraph (a)(1) of this section and intends to distribute the substance in commerce must submit a significant new use notice.

(2) [Reserved]

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